

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Atty. Cooper McDonald on 6/25/2009. The amended claims (received in the office 3/11/2009) will be entered.

**1) DELETE** claims 27-40.

## **DETAILED ACTION**

### **Application Priority**

This application is a 371 of PCT/EP03/06471, 6/18/2003, and claims priority to foreign application, Italy FR2002A000107, 6/19/2002.

### **REASONS FOR ALLOWANCE**

Applicants' arguments and declaration under CFR 1.132 by Dr. Guarna have been fully considered and found to be persuasive. Accordingly, the rejection of claims 22-25, 42 under 35 U.S.C. 103(a) as being unpatentable over Guarna et al. (Applicant-cited reference on IDS: Guarna et al. *J. Org. Chem.* 1999, 64, 7347-7364.), claims 22-25, 42 rejected under 35 U.S.C. 103(a) as being unpatentable over Cini et al (Eur J of Org Chem, March 2002, 873-880) are withdrawn. Claims 22-25 and 42 are free of prior art. An examiners amendment has been made to cancel claims 27-40. Claims 22-25 and 42 are renumbered as 1-5.

The following is an examiner's statement of reasons for allowance:

Claims 22-25, 42 are directed to a pharmaceutical composition comprising as active principle at least one compound among the 3-aza-bicyclo[3.2.1] octane derivatives of general formula (I) or mixtures thereof. The closest prior art of record to compounds of formula I are Guarna et al. (*J. Org. Chem.* 1999, 64, 7347-7364.) and Cini et al (Eur J of Org Chem, March 2002, 873-880). Guarna and Cini describe the synthesis of dipeptide isoteris (or isoters), termed BTAs or BTSSs, which may in turn be used to synthesize oligomers, as chiral auxiliaries, or as reverse turn inducers in peptide chains (Cini, page 873). The amide precursors of BTAs are BTAAOs in Guarna and are

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intermediates in the synthesis of dipeptide isoterres. The BTAAOs disclosed in Guarna and Cini are intermediates as they are made from simpler compounds and used for the later synthesis of more complex products, e.g., modified peptides and the references provide no specific pharmaceutical utility for the BTAAOs themselves. Claims 22-25 are directed to pharmaceutical compositions. These pharmaceutical compositions include a compound of formula I, as the active ingredient, and a pharmaceutically acceptable excipient. This invention is neither taught nor suggested by Guarna or Cini. Few compounds of formula I are taught in Guarna and in Cini but are disclosed as intermediates. M.P.E.P. § 2144.09 states: "[I]f the prior art merely discloses compounds as intermediates in the production of a final product, one of ordinary skill in the art would not ordinarily stop the reference synthesis and investigate the intermediate compounds with an expectation of arriving at claimed compound which have different uses" *In re Lahu*, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). Accordingly, there is no anticipation or motivation of making composition of formula I of the instant invention from the teaching or suggestion from prior art.

The claims are allowable over the closest art of record because they do not teach, disclose nor make obvious the claimed compositions of formula I.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

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